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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,225	09/04/2003	Werner Haberbosch	NY-HUBR-1183.1-DIV-US	5684
24972	7590	07/10/2006		EXAMINER
FULBRIGHT & JAWORSKI, LLP			AZPURU, CARLOS A	
666 FIFTH AVE			ART UNIT	PAPER NUMBER
NEW YORK, NY 10103-3198			1615	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/655,225	HABERBOSCH, WERNER	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 April 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 18-22 and 26-44 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 18-20, 26-31, 33, 35-37 and 39 is/are allowed.  
 6) Claim(s) 21-22, 32, 34, 38, and 40-44 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 04/24/2006.

The following rejections are maintained in this action:

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, 32, 34, 38 and 40-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The term "preventing" is objected to as not enabled by the instant specification as follows:

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The most pertinent factors involved are:

(1) The nature of the invention:

The invention involves a stent coating of 3-deazaadenosine and its use in treating and preventing reperfusion injury, restenosis, inflammatory and infectious coronary syndromes, dilated cardiomyopathy, Viral myocarditis or infections by parasites.

(2) The state of the prior art

The prior art recognizes increased expression of VCAM-1 and ICAM-1 in vessels showing atherosclerotic plaques.

(3) The relative skill of those in the art

The relative skill of the those in the art is high since experimentation requires Ph.D. or MD level analysis.

(4) The predictability or unpredictability of the art

The unpredictability of the peptide art is very high. While the data in the experimental section supports findings up after 35 days, there is no data to show that plaque formation would occur for any length of time after this.

(5) The breadth of the claims

The claims are very broad. The term prevention implies that plaque formation will never occur again. As stated above, the experimental data does not support this assertion.

(6) The amount of direction or guidance presented

The application does not give any guidance as to how long prevention would occur outside of the working examples.

(7) The presence or absence of working examples

The working examples of the specification involve a study of mice which are sacrificed after 35 days.

(8) The quantity of experimentation necessary

Since the significance of the use of 3-deazaadenosine in the long term prevention of any of these vascular injuries can not be predicted easily from the data presented, the ordinary practitioner would need to examine test animals for quite some time in order to support "preventing" any of the claimed conditions.

Claims 21-22, 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 sets out "infections by parasites" as something the claimed stent coating can treat. However, the specification does not set out the type of parasitic infections. Correction is requested.

***Response to Arguments***

Applicant's arguments filed 04/24/2006 have been fully considered but they are not persuasive.

Applicant does not argue the rejection of claims 21, 22, 32, 34, 38 and 40-44 under 35 USC 112, first paragraph for enablement, except to say a declaration would be filed. No declaration has been filed and the rejection is hereby maintained.

Regarding the rejection of claims 21-22, 41-44 under 35 USC 112, first paragraph for written description, applicant argues that the amendment of the claims overcomes the rejection. However, the amendment does nothing to correct the deficiency of the application. More specifically, the specification completely lacks any reference to a parasitic infection associated with the symptoms being treated. Applicant makes no statement pointing out where the specification does support this term. The rejection is therefore maintained.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

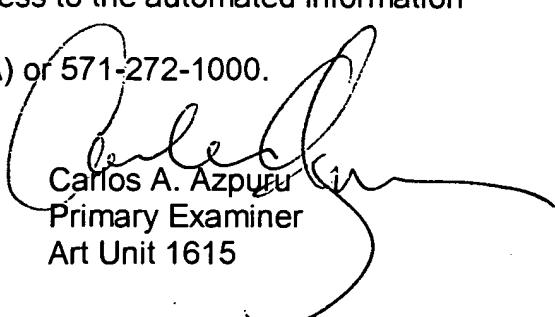
***Allowable Subject Matter***

As stated in the previous action, claims 18-20, 26-31, 33, 35-37, and 39 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

ca